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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/183,375	10/30/1998	JANOS SZEBENI	003/098/SAP	3056

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/183,375

Applicant(s)
Alving

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 11, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14, and 16-19 is/are pending in the application.
- 4a) Of the above, claim(s) 7-9, 11, 18, and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 14, 16, and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and the amendment dated 2-11-02 are acknowledged.

Claims included in the prosecution are 1-6, 10, 14 and 16-17. Claims 7-9, 11, 18 and 19 remain withdrawn as directed to non-elected invention.

Claim Rejections - 35 U.S.C. § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 2. Claims 1-6, 10, 14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharriere (5,744,156).**

Ko discloses a method of inhibiting complement activation by administering complement activation inhibitors. The method involves the administration of the inhibitor in controlled release delivery devices such as liposomes. The method is used for various conditions including the drug induced allergies and inflammation (note the abstract, col. 3,

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lines 49-52, col. 5, lines 32-51, col. 11, lines 1-42, examples and claims). Although Ko does not specifically teach the administration of the inhibitor together with the drug, it would have been obvious to one of ordinary skill in the art to administer together since Ko is suggestive of this combination from his statements on col. 10, line 42 et seq., according to which the inhibitor "can be combined with appropriate pharmaceutical formulation. An artisan would be motivated further to administer the drug or an agent which causes the side effects along with the inhibitor since the reference of De Lacharriere teaches such a concept; according to De Lacharriere hydroxy acids which cause side effects and the substance P antagonist which prevent these side effects are administered together. The criticality of cremophor (an amphiphilic compound) is unclear in the absence of unexpected results.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Ko teaches chimeric molecules which inhibit compliment activation and these proteins are taught to reduce the inflammation and that the conditions mentioned include those associated with ischemia-reperfusion, crash injury etc., and the table I referred to by the examiner are targets to try. This argument is not found to be persuasive since Ko is suggestive of the efficacy of the complimentation activation inhibitor and one skilled in the art would be motivated to use these with a reasonable expectation of success. Applicant argues that none in the table is an immediate complement reaction like that disclosed here in. This argument is not found to be persuasive since as applicant

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himself admits that Table does mention drug allergy. It would have been obvious to one of ordinary skill in the art that this expression means it is immediate (allergic reactions show up reasonably quickly) and that the complement activation inhibitor would act against the allergy whether the compounds which cause the hypersensitivity are classified as drugs or not since the inhibitor treats the symptoms. With regard to applicant's arguments that De Lacharriere does not teach hypersensitivity associated with complement activation by amphiphilic molecules, the examiner points out that De Lacharriere is combined to show that administration of compositions causing side effects together with those which reduce the side effects is routinely practiced in the art.

3. Claims 1-6, 10, 14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharriere (5,744,156), in further combination with applicant's statements of prior art.

Neither Ko nor De Lacharriere teach the use of cremophor as a drug or as a carrier. The references do not also teach that cremophors or liposomes cause complement activation. Applicant on pages 5 and 6 cite various references which show that cremophors and liposomes cause complement activation. Since the reference of Ko teaches that the inhibitors of complement activation for the treatment of conditions resulting from complement activation, it would have been obvious to one of ordinary skill in the art to use Ko's inhibitors for cremophor induced side effects since one would expect similar results irrespective of what causes the complement activation.

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This rejection is maintained since applicant provides no specific arguments.

- 4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

September 17, 2002